1 2 3	UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT
4	August Term, 2000
5 6	(Argued: November 7, 2000 Decided: March 01 2001)
7 8	Docket No. 00-7527
9	X
10	VITO MILANESE, JR. and SUZANNE MILANESE,
11	<u>Plaintiffs-Appellants</u> ,
12	- v
13	RUST-OLEUM CORPORATION,
14	<u>Defendant-Appellee</u> .
15 16	X Before: KEARSE, McLAUGHLIN, and STRAUB, <u>Circuit Judges</u> .
17	Plaintiffs appeal from an order of the United States
18	District Court for the Eastern District of New York (Mishler
19	$\underline{\mathtt{J.}}$), granting defendant's motion for summary judgment and
20	denying plaintiffs' cross-motion seeking leave to amend the
21	complaint.
22	AFFIRMED IN PART, REVERSED IN PART, VACATED AND REMANDED.
23 24 25	JAY L. FEIGENBAUM, Finz & Finz, P.C., Jericho, New York, <u>for</u> <u>Plaintiffs-Appellants</u> .

MICHAEL B. SENA, Silbert, Hiller & Sena, L.L.P., New York, New York, for Defendant-Appellee.

McLAUGHLIN, Circuit Judge:

5 BACKGROUND

Vito Milanese, Jr. ("Milanese") was the co-owner of a small landscaping business. His amour propre, however, was his Ferrari 308. In December 1996, he dedicated his evenings to rust-proofing the chassis. This tedious operation required wire-brushing the entire under-body of the car, then applying a rust-preventing primer coat, followed by a coat of enamel. For use in priming and painting, Milanese bought a can of Rust-Oleum Rusty Metal Primer (the "Primer") and a can of Rust-Oleum Protective Enamel (the "Enamel"). While using the primer, vapors were ignited by the flame in an adjacent woodburning stove, causing a flash fire that severely burned

• The Can of Primer

On the front of the Primer can appeared the following warning in red, bold letters: "DANGER: EXTREMELY FLAMMABLE.

CONTENTS UNDER PRESSURE. VAPOR HARMFUL." The directions for use on the back of the can stated: "Use outdoors, or in a well-ventilated area, when temperature is above 50E F (10E C)

and humidity is below 85% to ensure proper drying. Avoid spraying in very windy, dusty conditions."

On the back of the Primer can the following precautions also appeared:

CONTAINS TULUOL AND XYLOL. Keep away from heat, sparks and flame, including pilot lights and cigarettes. Avoid over-exposure to vapors. To avoid breathing vapors or spray mist, open windows and doors or use other means to ensure fresh air entry during application and drying. If you experience eye watering, headaches or dizziness, increase fresh air or wear respiratory protection (NOSH/MSHA TC 23E C or equivalent), or leave the area. Avoid contact with skin. DO NOT puncture or incinerate.

• The Can of Enamel

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 In contrast, the warning on the front of the Enamel can stated, in red bold letters: "DANGER! EXTREMELY FLAMMABLE LIQUID & VAPOR. VAPORS MAY CAUSE FLASH FIRE. CONTENTS UNDER PRESSURE." (emphasis added). Although the directions for use on the back were similar to those on the can of Primer, additional precautions were listed on the back of the Enamel can:

Vapors may ignite explosively. Keep away from heat, sparks and flame. Extinguish all flames and pilot lights, and turn off stoves, heaters, electric motors and other sources of ignition during use and until all vapors are gone. Do not smoke. Use only with adequate ventilation. Prevent build-up of vapors by opening all windows and doors to achieve cross-ventilation. Do not expose to heat or store at temperatures above 120E F. Exposure to heat or

prolonged exposure to sun may cause bursting. Do not puncture or incinerate (burn) container. (emphasis added).

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The two products were packaged together in a blue plastic wrapper. It is unclear from the record what warnings, if any, appeared on the plastic packaging itself. Milanese was familiar with the individual warning labels because he had used both products on numerous occasions and had recently read each label.

On December 10, 1996, as he had done often, Milanese went out to his garage to work on his Ferrari. The garage was detached from his house, was approximately 12 feet x 18 feet in size, and was heated by a wood-burning, pot-belly stove.

On this night, Milanese intended to scrape and prime (but not paint) the car's wheel wells.

The Ferrari was parked front-end in, with its rear wheels closest to the garage door, and its front-passenger side near the wood-burning stove. Having previously compared the Primer label with the Enamel label, Milanese concluded that, as long as he did not use the Primer near the pot-belly stove, he need not put out the fire that was fully enclosed in the stove before using the Primer. In addition to two large air vents in the rafters, Milanese cranked open two small windows on the

wall of the garage nearest the stove. He did not open the garage door.

He then began to scrape and prime the wheel wells, beginning with the front driver-side, then moving counter-clockwise to the rear driver-side and the rear passenger-side. Ten minutes after he began to spray the Primer onto the rear passenger-side wheel well, vapors from the Primer licked the fire in the stove approximately 10 feet away, triggering a flash fire that engulfed Milanese in flames. Milanese sustained second and third degree burns to more than 36% of his body. He is permanently disfigured and scarred.

In August 1998, Milanese commenced this action against the Rust-Oleum Corporation ("Rust-Oleum") in the United States District Court for the Eastern District of New York (Mishler, J.), alleging common law claims for breach of warranty, strict products liability, and negligence. The crux of each cause of action was that Rust-Oleum failed to warn on the Primer's label - as compared with the Enamel label - that its vapors could cause flash fire. Milanese's wife also asserted a claim for loss of consortium.

In November 1999, upon completion of discovery, Rust-Oleum moved for summary judgment on the ground that the Milaneses' claims were preempted by the Federal Hazardous Substances Act (FHSA), 15 U.S.C. §§ 1261-1278, and certain regulations promulgated thereunder, 16 C.F.R. §§ 1500.1-.272. Milanese cross-moved for leave to amend the complaint to add a cause of action alleging that Rust-Oleum negligently failed to comply with the FHSA. In particular, the claim would allege that the Primer can failed to identify vapor flash fires as a "principal hazard" and failed to list the necessary "precautionary measures," in violation of 15 U.S.C. § 1261(p)(1).

To support his cross-motion, Milanese attached the deposition testimony of a Rust-Oleum employee, Larry West, a Safety and Industrial Hygiene Coordinator. West had admitted that: (1) the same propellant is used in both the Primer and Enamel; (2) the propellant, which is a vapor, is extremely flammable; and (3) vapors from the Primer (which include both the propellant contained in the liquid primer itself and the vapors that are emitted from the liquid once it has been sprayed onto a surface) may cause flash fires. When asked to explain why, unlike the Primer can, the Enamel can warned that both the liquid Enamel and its vapors were flammable and that the vapor may cause flash fires, West answered that the Enamel was in "a later generation can;" and he speculated that the Enamel may contain a raw material that makes it more flammable

than the Primer. West contended that the very warning "EXTREMELY FLAMMABLE" on the Primer can implied that both the liquid primer and its vapors were flammable, and that the precautions regarding proper ventilation adequately protected the consumer from the flash fire hazard.

Milanese also attached the affidavit of Robert J. Cunitz, Ph.D., a certified Human Factors Psychologist. Mr. Cunitz stated that he had "expertise in the area of product design, product warnings[,] product safety information and safety labeling," and was familiar with the requirements mandated by the FHSA. Based on his review of Milanese's and West's testimony, videotapes of the spray cans at issue, transcribed text of the warnings and labels on each can, and Material Safety Data Sheets produced by Rust-Oleum, Mr. Cunitz concluded in his "expert opinion that Rust-Oleum Corporation did not properly comply with the provisions of the FHSA." Specifically, he considered the Primer can to be a misbranded product under the FHSA because the principal hazard associated with the product, namely that "vapor may cause flash fire," nowhere appeared on the product's label.

The district court granted Rust-Oleum's motion for summary judgment, denied Milanese's cross-motion to amend, and dismissed the complaint. Specifically, the court held that:

(1) Mr. Cunitz's affidavit was inadmissible because he failed to submit proof of his qualifications to express an opinion as to whether the Primer can was "misbranded" within the meaning of the FHSA; (2) the Primer label was fully compliant with the FHSA; (3) Milanese's failure to warn claims were therefore preempted; and (4) granting leave to amend the complaint would be futile because the evidence offered by Milanese merely supported the argument that the Primer warning should have been more explicit – a claim that is preempted – rather than a claim that the warning failed to comply with the FHSA's requirements.

Milanese now appeals, arguing that the district court erred in granting summary judgment because West's deposition testimony created genuine issues of material fact. Milanese identified those issues as: (1) whether vapor flash fire is a principal hazard distinct from, and in addition to, the flammability of the liquid Primer; (2) if so, whether the Primer can identified this principal hazard and contained the necessary precautionary measures, as required by the FHSA, 15 U.S.C. § 1261; and (3) whether the Enamel can, when packaged together with the Primer can, misled the consumer into believing that vapor flash fire, while admittedly a danger when using the Enamel, was not a hazard when using the Primer.

1 Milanese also contends that the district court erred by 2 denying him leave to amend his complaint.

For the reasons set forth below, we affirm in part, reverse in part, vacate and remand.

DISCUSSION

I. <u>Preemption Under the FHSA</u>

We review the district court's grant of summary judgment de novo, drawing all inferences and resolving all ambiguities in favor of the non-movant. Parker v. Columbia Pictures

Indus., 204 F.3d 326, 332 (2d Cir. 2000). Summary judgment is appropriate only if the admissible evidence establishes that "there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c).

The Primer used by Milanese is concededly a hazardous substance sold for household use. As such, it is regulated by the FHSA. 15 U.S.C. § 1261(f)(1)(A)(v) (defining a hazardous substance as "[a]ny substance or mixture of substances which . . . is flammable or combustible.").

The FHSA was enacted in 1960 to "provide nationally uniform requirements for adequate cautionary labeling of packages of hazardous substances which are sold in interstate commerce and are intended or suitable for household use."

House Comm. On Interstate and Foreign Commerce, Federal
Hazardous Substances Labeling Act, H.R. Rep. No. 1861, 86th
Cong., 2d Sess. 2 (1960), reprinted in 1960 U.S.C.C.A.N. 2833,
2833. A limited preemption provision was added in 1966. It
provides that:

if a hazardous substance or its packaging is subject to a cautionary labeling requirement under [15 U.S.C. §§ 1261(p) or 1262(b)] designed to protect against a risk of illness or injury associated with the substance, no State . . . may establish or continue in effect a cautionary labeling requirement applicable to such substance or packaging and designed to protect against the same risk of illness or injury unless such cautionary labeling requirement is identical to the labeling requirement under [15 U.S.C. §§ 1261(p) or 1262(b)].

Act of Nov. 3, 1966, Pub. L. 89-756, § 4(a), 80 Stat. 1305, renumbered and amended, Act of Nov. 6, 1969, Pub. L. 94-284, § 17(a), 90 State. 510, reprinted at 15 U.S.C. § 1261 Note (b)(1)(A) "Effect upon Federal and State Law." See also id. at (b)(1)(B) (prohibiting states from establishing cautionary labeling requirements that are not identical to those contained in the regulations promulgated by the Consumer Product Safety Commission ("CPSC") in accordance with the FHSA).

In light of these express provisions, Milanese concedes that the FHSA preempts any state cause of action that seeks to impose a labeling requirement different from the requirements

2 Although we have not previously so held, we do so now and join many of our sister circuits. E.g., Comeaux v. Nat'l Tea Co., 3 81 F.3d 42, 44 (5th Cir. 1996); Moss v. Parks Corp., 985 F.2d 4 736, 740 (4th Cir.), cert. denied, 509 U.S. 906 (1993); 5 6 Pennsylvania General Ins. Co. v. Landis, 96 F. Supp. 2d 408, 414-15 (D.N.J. 2000), aff'd, ___ F.3d ___ (3d Cir. Nov. 21, 7 2000) (TABLE, No. 00-1731); <u>Kirstein v. W.M. Barr & Company</u>, 8 <u>Inc.</u>, 983 F. Supp. 753, 761 (N.D. Ill. 1997), <u>aff'd</u>, 159 F.3d 9 1065 (7th Cir. 1998), cert. denied 526 U.S. 1065 (1999). 10 11 Therefore, to the extent that Milanese's claims for breach of express warranty, strict products liability, and negligence 12 seek to impose additional or more elaborate labeling 13 requirements on Rust-Oleum, we fully agree with their 14 15 dismissal by the district court on preemption grounds.

found in the FHSA and the regulations promulgated thereunder.

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We agree with Milanese, however, that a state cause of action alleging non-compliance with the FHSA would not be preempted by the Act. Torres-Rios v. LPS Labs., Inc., 152

F.3d 11, 13 (1st Cir. 1998); Moss, 985 F.2d at 740; Landis, 96

F. Supp. 2d at 415; Kirstein, 983 F. Supp. at 761. Although there is no federal private right of action under the FHSA, Riegel Textile Corp. v. Celanese Corp., 649 F.2d 894, 903 (2d Cir. 1981), a state negligence claim lies for failure to

1 comply with the federal, FHSA-mandated labeling requirements.

<u>Wallace v. Parks Corp.</u>, 212 A.D.2d 132, 140, 629 N.Y.S.2d 570,

576 (4th Dep't 1995).

II. Leave to Amend the Complaint

In opposition to Rust-Oleum's motion for summary judgment, Milanese cross-moved for leave to amend his complaint to add a claim for non-compliance with the FHSA. The district court denied this motion, concluding that the amendment would be futile because, as a matter of law, the Primer can complied with all necessary labeling provisions of the FHSA and related regulations. We disagree.

We review the district court's denial of leave to file an amended complaint for abuse of discretion. Jones v. New York Div. of Military and Naval Affairs, 166 F.3d 45, 49 (2d Cir. 1999). A district court abuses its discretion if it bases its ruling on a mistaken application of the law or a clearly erroneous finding of fact. Cooter & Gell v. Hartmarx Corp., 496 U.S. 384, 405 (1990). Leave to file an amended complaint "shall be freely given when justice so requires," Fed. R. Civ. P. 15(a), and should not be denied unless there is evidence of undue delay, bad faith, undue prejudice to the non-movant, or futility. Foman v. Davis, 371 U.S. 178, 182 (1962). Here, the district court believed it would be futile to allow

Milanese to amend his complaint because the proposed claim of non-compliance with the FHSA could not withstand an inevitable motion for summary judgment.

Milanese argues that the district court applied the wrong standard by measuring the proposed amendment against a summary judgment yardstick. He contends that a plaintiff should be allowed to amend his complaint so long as the proposed complaint on its face states a valid claim, and could therefore withstand a motion to dismiss under Fed. R. Civ. P. 12(b)(6). Milanese is incorrect.

It is true that when a cross-motion for leave to file an amended complaint is made in response to a motion to dismiss under Fed. R. Civ. P. 12(b)(6), leave to amend will be denied as futile only if the proposed new claim cannot withstand a 12(b)(6) motion to dismiss for failure to state a claim, i.e., if it appears beyond doubt that the plaintiff can plead no set of facts that would entitle him to relief. Ricciuti v. N.Y.C. Transit Auth., 941 F.2d 119, 123 (2d Cir. 1991). However, the rule is different where, as here, the cross-motion is made in response to a Fed. R. Civ. P. 56 motion for summary judgment, and the parties have fully briefed the issue whether the proposed amended complaint could raise a genuine issue of fact and have presented all relevant evidence in support of their

positions. In the latter situation, even if the amended complaint would state a valid claim on its face, the court may deny the amendment as futile when the evidence in support of the plaintiff's proposed new claim creates no triable issue of fact and the defendant would be entitled to judgment as a matter of law under Fed. R. Civ. P. 56(c). See Azurite Corp. v. Amster & Co., 844 F. Supp. 929, 939 (S.D.N.Y. 1994) (denying plaintiff leave to amend complaint where proposed amendment "would be futile because the factual foundations of [its] new allegations are insufficient, as a matter of law, to withstand defendants' motion for summary judgment"), aff'd, 52 F.3d 15 (2d Cir. 1995); Health-Chem Corp. v. Baker, 915 F.2d 805, 810 (2d Cir. 1990); Cf. Hemphill v. Schott, 141 F.3d 412, 420 (2d Cir. 1998) (applying summary judgment standard and allowing amendment).

Here, Rust-Oleum moved for summary judgment on the ground that Milanese's claims are preempted because Rust-Oleum's Primer label complied with the FHSA as a matter of law.

Milanese cross-moved for leave to amend his complaint to add a claim that the Primer label did not comply with the FHSA. In opposition to Rust-Oleum's motion and in support of his cross-motion, Milanese presented evidence of Rust-Oleum's non-compliance with the Act. Under these circumstances, the

district court correctly applied the summary judgment standard set forth in Fed. R. Civ. P. 56(c) - and not the Fed. R. Civ. P. 12(b)(6) standard for failure to state a claim - to determine whether granting Milanese leave to amend his complaint would be futile.

A. <u>Misbranding Under the FHSA</u>

A manufacturer violates the FHSA if it "introduc[es] into interstate commerce . . . any misbranded hazardous substance."

15 U.S.C. § 1263(a). A hazardous substance is "misbranded" if its packaging or labeling "is in violation of an applicable regulation issued" under the Act, "or if such substance . . . fails to bear a label— (1) which states conspicuously . . . (E) an affirmative statement of the principal hazard or hazards, such as 'Flammable', 'Combustible', 'Vapor Harmful' . . . or similar wording descriptive of the hazard; [and] (F) precautionary measures describing the action to be followed or avoided" 15 U.S.C. §§ 1261(p)(1)(E) and (F). See also 16 C.F.R. § 1500.127 (requiring labels of products with multiple hazards to contain "[a]n affirmative statement of each such hazard; [and] the precautionary measures describing the action to be followed or avoided for each such hazard").

Milanese argues that the Primer was "misbranded" in two ways: (1) the label on the Primer can itself failed to warn of the principal hazard of vapor flash fire and failed to state the precautionary measures necessary to avoid this hazard; and (2) when packaged together with the Enamel, the Primer label effectively disclaimed vapor flash fires as a principal hazard and misled the consumer into believing that he need not extinguish all sources of ignition prior to its use. We address each argument in turn.

1. Compliance of the Primer Label Standing Alone

Milanese contends that the Primer can does not contain a warning of the principal hazard that "VAPORS MAY CAUSE FLASH FIRE," as distinct from the hazard that the <u>liquid</u> itself is extremely flammable. Nor does the Primer label say "EXTREMELY FLAMMABLE <u>LIQUID & VAPOR</u>." In contrast, the Enamel can does.

In addition, unlike the Enamel, the Primer can does not tell the user to "[e]xtinguish all flames and pilot lights, and turn off stoves, heaters, electric motors and other sources of ignition during use and until all vapors are gone," or to use adequate ventilation to "[p]revent build-up of vapors" in connection with the risk of flash fires as distinct from vapor inhalation concerns. Rust-Oleum counters that the two words: "EXTREMELY FLAMMABLE," in and of themselves,

pertain to <u>both</u> the liquid and vapors, and that the warning "VAPOR HARMFUL" together with the instructions to "[k]eep away from heat, sparks and flame, including pilot lights and cigarettes," and to "open windows and doors or use other means to ensure fresh air entry during application and drying," adequately instruct the consumer on how to avoid the hazard of flash fire.

Although the district court correctly held that the Cunitz affidavit was inadmissible (a ruling that Milanese does not seriously challenge on appeal), see Fed. R. Evid. 104 and 702, the court erred in concluding that Milanese provided nothing more than conclusory allegations to support his claims. The additional evidence presented by Milanese in opposition to Rust-Oleum's motion for summary judgment, specifically the testimony of Larry West and the text of the labels on the Primer and Enamel cans, constituted substantial evidence of the specific risk of vapor flash fire associated with the use of the Primer as an additional hazard distinct from the flammability of the liquid product.

There exists, therefore, a material issue of fact as to whether the danger of flash fire caused by the vapors is a primary hazard that is separate and distinct from the flammability of the liquid product. If so, the Primer label

complies with the FHSA only if it "states conspicuously
an affirmative statement of [this] principal hazard [and
the necessary] precautionary measures describing the action to
be followed or avoided " 15 U.S.C. §§ 1261(p)(1)(E)
and (F). Assuming that flash fire from the Primer <u>vapor</u> is a
hazard distinct from the flammability of the <u>liquid</u> product,
we cannot hold that, as a matter of law, the Primer can fully
complies with the FHSA. <u>Cf. Landis</u> , 96 F. Supp. 2d at 416-18
(holding that, as a matter of law, lacquer thinner label which
cautioned: "EXTREMELY FLAMMABLE LIQUID AND VAPOR Vapors
may ignite explosively. VAPORS MAY CAUSE FLASH FIRE
Turn off and extinguish all flames and pilot lights on stoves,
heaters, water heaters, etc. Disconnect all electric motors
and other sources of ignition during use and until all vapors
are gone," warned of vapor flash fire as a principal hazard
apart from the flammability of the liquid product); Kirstein ,
983 F. Supp. at 756, 762-64 (same result with similar language
on product label).1

¹ In support of its argument that the Primer label complies with the FHSA as a matter of law, Rust-Oleum primarily relies (as did the district court) on the Fourth Circuit's decision in Moss, 985 F.2d at 742. That decision, which obviously is not binding on this Circuit, is distinguishable from the present case for several reasons. For example, it involved only a single container that was not packaged with a second container bearing different warnings that, as is the case (continued...)

To determine whether a product complies with the FHSA labeling requirements as to the principal hazard of vapor flash fire, courts often compare the product's label with that previously required by the Consumer Product Safety Commission to be placed on extremely flammable contact adhesives:

DANGER. EXTREMELY FLAMMABLE. VAPORS MAY CAUSE FLASH FIRE. Vapors may ignite explosively. Prevent buildup of vapors-open all windows and doors-use only with cross-ventilation. Keep away from heat, sparks, and open flame. Do not smoke, extinguish all flames and pilot lights, and turn off stoves, heaters, electric motors, and other sources of ignition during use and until all vapors are gone. Close container after use.

16 C.F.R. § 1500.133(b) (emphasis added)²; <u>Landis</u>, 96 F. Supp. 2d at 417-18; <u>Kirstein</u>, 983 F. Supp. at 763-64; <u>Canty v. Ever-Last Supply Co.</u>, 685 A.2d 1365, 1378 (N.J. Super. Ct. Law Div. 1996). According to the CPSC, this warning language was "the minimum cautionary labeling adequate to meet the requirements

^{(...}continued)

here, may have affected the message conveyed by the warnings on the first container. Further, the plaintiff in Moss principally argued that the statement of precautionary measures on the product was not sufficiently explicit or detailed, rather than that it failed to warn of the principal hazard of vapor flash fire as distinct from the general combustibility of the product. <u>Id.</u> at 742.

² This labeling provision was revoked as to extremely flammable contact adhesives after June 13, 1978 because the CPSC issued a regulation banning these products as of that date. 16 C.F.R. § 1500.133(e).

of [15 U.S.C. § 1261(p)(1)]." 16 C.F.R. § 1500.133(b). None of the emphasized language appears on the Primer label.

"VAPOR MAY CAUSE FLASH FIRE" is not necessarily required by the Act, the court found that the label adequately warned of this hazard only because it contained additional warnings not present on Rust-Oleum's Primer can. Torres-Rios, 152 F.3d at 13-15 (label of cleaner was found to adequately warn of danger of flash fire only because it also stated: (1) "Prevent buildup of vapors - use adequate cross-ventilation" in the context of vapors' explosive nature rather than health concerns of inhaling vapors; and (2) "turn off all sources of ignition during use and until vapors are gone;" and product came with a Material Safety Data Sheet that explicitly warned of the danger of flash fire and the precautions to take to avoid that danger.).

Because there are genuine issues of material fact as to:

(1) whether vapor flash fire is a principal hazard distinct

from, and in addition to, the flammability of the liquid

Primer; and (2) if so, whether the Primer can identified this

principal hazard and the necessary precautionary measures as

required by the FHSA, 15 U.S.C. § 1261, the district court

erred in concluding that granting leave to add a noncompliance claim would be futile.

2. <u>Non-Compliance of the Primer/Enamel Combination</u> <u>Package</u>

Even if the warnings and precautions on the can of Primer, considered in isolation, were found adequately to encompass the hazard of vapor flash fire, Milanese has stated an alternative claim based upon the packaging of the Primer and the Enamel as one unit.

As noted above, a hazardous substance is "misbranded" if its packaging or labeling "is in violation of an applicable regulation issued" under the Act, "or if such substance . . . fails to bear a label (1) which states conspicuously . . . an affirmative statement of the principal hazard or hazards . . . [and] precautionary measures describing the action to be followed or avoided." 15 U.S.C. §§ 1261(p)(1)(E) and (F). The term "label" is defined as "a display of written, printed, or graphic matter upon the immediate container of any substance." 15 U.S.C. § 1261(n) (emphasis added).

There is no dispute that the hazardous substance that injured Milanese was the Primer - not some combination of the Primer and the Enamel - and that the "immediate container" of the Primer, <u>i.e.</u>, the can, contained its own warnings and list

of precautions. However, the section of the Act that defines 1 the term "label" goes on to state that:

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a requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears (1) on the outside container or wrapper, if any there be, unless it is easily legible through the outside container or wrapper³ and (2) on all accompanying <u>literature</u> where there are directions for use, written or otherwise.

Id. (emphasis added). In addition, 16 C.F.R. § 1500.122 provides:

A hazardous substance shall not be deemed to have met the requirements of . . . [15 U.S.C. §§ 1261(p)(1) and (2)] if there appears in or on the label (or in any accompanying literature); words, statements, designs, or other graphic material that in any manner negates or disclaims any of the label statements required by the act

Although it was this Court's own research that unearthed these provisions, Milanese has <u>always</u> claimed that the label on the Enamel can (mentioning vapor flash fires) accompanying

³ There is some evidence in the record suggesting that the blue plastic packaging in which the cans of Primer and Enamel were wrapped may have contained its own warning. However, the record is not fully developed on this issue. It is also unclear whether the warnings on the cans themselves could be read through the plastic. Although the allegations of misbranding in Milanese's proposed amended complaint could be read to encompass a claim based on the outside packaging, such an argument was not made by Milanese in the briefs submitted below or on appeal and, therefore, will not be considered here.

the Primer can (mentioning only inhalation risks of vapors)
had the effect of suggesting that there was no particular risk
of flash fire when using just the Primer. In other words,
Milanese appears to argue that the Enamel label "negates or
disclaims . . . statements required by the act" to be
contained on the Primer label.

Such a claim, of course, was not addressed by Rust-Oleum in its motion for summary judgment, or by the district court in its decision below. Therefore, on remand, the district court must analyze this claim under the traditional futility standard, i.e., whether it would withstand a motion to dismiss under Fed. R. Civ. P. 12(b)(6). If the court concludes that Milanese has stated a valid claim for misbranding in this respect, it should allow this claim to be included in Milanese's amended complaint.

B. <u>Existence of Bad Faith</u>, <u>Undue Delay or Prejudice</u>

The district court did not find, and there is no evidence of, bad faith on the part of Milanese, undue delay or undue prejudice to Rust-Oleum should these amendments be allowed.

Rust-Oleum has been aware of the existence of the FHSA and its obligation to comply with its labeling requirements since the commencement of the litigation. Indeed, it raised preemption as an affirmative defense in its answer, and moved for summary

judgment on the ground that it fully complied with the FHSA's labeling requirements. Accordingly, no reason justifies the denial of Milanese's cross-motion seeking leave to amend the complaint. Hemphill, 141 F.3d at 420.

5 CONCLUSION

We have considered the parties' remaining contentions and find them to be without merit. Accordingly, we AFFIRM the grant of the defendant's motion for summary judgment dismissing Milanese's claims insofar as they seek to impose additional labeling requirements on Rust-Oleum beyond those provided under the FHSA and regulations promulgated thereunder. We REVERSE the denial of Milanese's cross-motion seeking leave to amend, VACATE the judgment entered below dismissing the action, and REMAND for further proceedings consistent with this opinion.